EXHIBIT A

IN THE CIRCUIT COURT OF

THE SEVENTEENTH JUDICIAL CIRCUIT, IN

AND FOR BROWARD COUNTY, FLORIDA

CLARE AUSTIN, Plaintiff,) Case No. CACE-15-008373

v.)

C.R. BARD, INC., a foreign corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.)

Do Not Disclose - Subject to Further Confidentiality Review

VIDEOTAPED DEPOSITION OF KRISHNA KANDARPA, M.D.

BETHESDA, MARYLAND

THURSDAY, JULY 19, 2018

12:57 P.M.

Pages: 1 - 237

Reported by: Leslie A. Todd

Q All right. Doctor, did there come a time when you were the director of radiology at the University of Massachusetts when a company by the name of Bard and a company by the name of Austin Biomedical Associates selected you to act as the medical monitor for a study known as the EVEREST Study?

A Yes.

Q All right. And you understand we're here to talk to you about your role as the medical monitor in that study and to also talk about the G2 filter?

A Mm-hmm.

Q Is that a "yes"?

A Yes.

Q All right. What were your responsibilities as the medical monitor for this study?

A Okay. So my responsibility was primarily to Boston Biomedical Associates, and I was a medical monitor. I was hired as a medical monitor, and I was to adjudicate events reported by the investigator, and to -- and to say whether they -- the investigator correctly attributed

whatever the problem was to either the filter or something unrelated to the filter. So I went over all those cases and made that determination.

Q All right. Let's back up a step. If you would, tell us what the EVEREST Study was.

A Okay. The EVEREST Study was a retrievability study for a filter that Bard had called the G2 filter, which was originally, I came to find out, was approved as a permanent filter, but they wanted to make it retrievable or an option to retrieve, and so they did the EVEREST Study of a hundred patients.

Q All right. And when you describe this as a retrievability study, tell us what you mean by that.

A Okay. So we generally feel that -- that when patients need filters, there comes a time when they may no longer need the filter to filter the clots as they come in from the legs. At that point there is a medical determination made that this can be removed -- the filter can be removed.

Prior -- prior filters, the original filters were not designed to be taken out. So around that time that I was monitoring the study

put in or taken out, if that were the case, and if it was appropriately put in. And then you would determine if the person said, let's say, the filter got -- caught a clot, then you would look at the images, and you would say, Yes, I agree the filter got -- stopped a clot. So that's the way you do it.

Or if you say, I don't see the clot, then you go back to the investigator and say, Where is the clot? He might have sent you the wrong film or whatever, but we work it out that way. That's typically the way it worked.

Q Would you look at patient records?

A Yes.

Q Would you look at --

A If I had to. If I had to probe into it, I would, yes.

Q All right. But patient records were available to you for review?

A Yes. Mm-hmm.

Q Were what I call imaging studies available to you for review?

A When I wanted them, yes.

Q All right.

A Or sometimes even when I didn't want them.

Q All right. What else would have been available to you for review as your role or as your work as the medical monitor?

A Basically the study reports and anything that I thought I wanted was usually provided to me.

Q Were you provided with documents known as adverse event summaries as part of your work in this study?

A Yes. So every time we met, we'd have a summary list of adverse events, and then we would go to that list, and -- and then I would determine whether that had actually -- was an adverse event or not.

Q Were you also provided with a document known as a device observation summary?

A I'm having trouble distinguishing the two, but, yes, general information was made available to me.

Q So that information was provided to you as your work as the medical monitor in this retrievability study.

MR. JOHNSON: Can you read back the question two questions ago.

(Whereupon, the requested record was read.)

BY MR. JOHNSON:

Q I think it's based on what you saw, did you develop a belief as to whether a reasonable physician would want to know about the observations that you were making in your role as the medical monitor in this study?

A Yes -- yes to that.

Q Yes?

A Yes. To that, yes.

(Kandarpa Exhibit No. 2 was marked for identification.)

BY MR. JOHNSON:

Q All right. Doctor, I'm going to hand you what I've marked as Exhibit --

A 2.

Q -- 2.

MR. NORTH: Do you have another copy?

THE WITNESS: I only have one. It's here if you want.

MR. NORTH: Okay.

Or any further down from where it was, yeah.

BY MR. JOHNSON:

Q All right. Filter tilt, what does that mean?

MR. NORTH: Objection to the form. Seeks expert opinion.

BY MR. JOHNSON:

Q Doctor, as part of your role in this case as the medical monitor, were you evaluating this filter as it relates to tilt?

A Yes, I was.

Q Okay. What does "filter tilt" mean?

A Okay. Well, the implications of filter tilt, if you look at a filter that's deployed properly and you look at it head on within the interior vena cava, you know, a cross-section if you will, you will see that a certain -- there is a certain area that is restricting the clots. What happens when the filter tilts is that those areas increase -- I mean there are studies on this -- and so larger clots can go through.

And in its extreme, it could -- it's not doing -- it's not functioning at all, and --

A Well, filter fracture generally --

MR. NORTH: Objection to the form.

THE WITNESS: Generally means --

BY MR. JOHNSON:

Q Let me reask the question, Doctor.

A Okay.

Q As your role in this retrievability study as the medical monitor, were you looking for and assessing filter fracture as an adverse event?

A Yeah, because -- yes, I was. Yeah.

Q And tell us what "filter fracture" is.

A Okay. So filter fracture is when one of the components of the filter breaks away. It may -- for example, a leg can break, but the two pieces could be still in place sort of, just away from each other. Sometimes they can fracture to a degree that, you know, the filter can no longer do its job. And occasionally a fragment might end up in the heart, which you don't want either.

Q All right. Filter migration, filter tilt, filter perforation and fracture of the filter, are those all examples of adverse events that you were looking for as the medical monitor during this retrievability study?

the things obviously that we look for and made sure that there wasn't an undue amount of that.

BY MR. JOHNSON:

Q Did you form a belief as the medical monitor that there was an association between filter migration, filter tilt, and perforation of the filter through the vena cava?

MR. NORTH: Objection to the form.

THE WITNESS: I didn't form -- I didn't form that opinion because of the study. It's something that happens that's generally known that you don't want that because these are the consequences of a migrating filter. Okay. So I -- I consciously probably didn't say it, but I sort of understood that that was what was going on.

BY MR. JOHNSON:

Q Okay. Did you -- are you saying you understood that was going on with the G2 filter?

A Yes.

MR. NORTH: Objection to the form.

THE WITNESS: In the study, yes.

BY MR. JOHNSON:

Q Okay. This retrievability study, was it

Q All right.
A So being that this was probably one of the early ones, that's why you're seeing so many.
Q And just, again, define some terms for us. Is that a patient identification number 01-001?
A Yeah.
Q And so this document would have been provided to you as part of what you did in your role as the medical monitor?
A Correct.
Q All right. And it says "extravascular penetration of the IVC." What does that mean?
A The very first patient, that means that the -- it would imply to me that IVC legs most likely went way -- through the wall of the inferior vena cava.
Q And it goes on to say that: "The tip of the medial arm of the filter is 5 millimeters uncorrected beyond the contrast column of the IVC."
A Right.
Q Again, what does that mean?
A Okay. So when --

retrievability study?

MR. NORTH: Objection to the form.

THE WITNESS: Well, I -- I can't speak to what the IFU should have said or the -- but I can tell you the expectation of the physician is that we've been told that truth -- the entire truth about it and we can make our own judgments. So, yes, a reasonable and practicing physician would want to know all -- all the details.

BY MR. JOHNSON:

Q All right. Let me rephrase the question.

As the medical monitor having seen and observed the migrations associated with the G2 filter, do you have a belief as to whether a reasonable physician would want to know about the totality of these migrations?

A Yes.

MR. NORTH: Objection to the form.

THE WITNESS: I would think they would want to know.

BY MR. JOHNSON:

Q Why do you believe a reasonable physician would want to know that information?

Q Now, when you were the medical monitor for this study, you did not conduct a literature review at that time of any published studies regarding the G2 filter or other retrievable filters, correct?

A No, I didn't, because that wasn't my task yet.

Q And you did not make an attempt to look at the medical literature to assess how Bard's complication rates were comparing to those of other manufacturers' filters, did you?

A Because they were not available, no, I did not.

Q And Bard never put any pressure or twisted your arm concerning your adjudication of these adverse events, did they?

A No.

MR. NORTH: Do you have any --

(A discussion was held off the record.)

(Kandarpa Exhibit No. 12 was marked for identification.)

BY MR. NORTH:

Q If I could, Doctor, let me hand you what's been marked as Exhibit 12.

A Okay.
Q Are you familiar with this document?
A Adjudication Manual of Operations, yep. Yeah.
Q And if we could turn to page 3 of 68.
A Okay.
Q Does that define what your responsibilities were --
A Yep.
Q -- as the medical monitor?
A You mean the bottom three that says "Roles and Responsibilities"?
Q Yes.
A "Establish adverse event complication definition." Yep. "Review and adjudicate complications as --

THE REPORTER: Excuse me. I'm going to need you to either read out loud --

THE WITNESS: Read it louder? Oh, you mean slow down?

THE REPORTER: Or just read to yourself.

THE WITNESS: I'll read it to myself.

Yeah, that seems about correct, yeah.

BY MR. NORTH:

Q And that was what you were provided by BBA as officially defining what your role in this study --

A Correct.

Q -- would be, correct?

A Mm-hmm.

Q And -- I'm sorry, yes or no?

A Yes, yes.

Q And the first primary responsibility was to establish definitions for adverse event complications, correct?

A Yes.

Q And the second role or primary responsibility was to review and adjudicate complications and adverse events as they occur, correct?

A Correct.

Q And then the third, which was somewhat related primary responsibility, was to review and adjudicate device malfunctions and filter imaging assessments, correct?

A Correct.

Q Doctor, in your work at NIH, you don't deal with IVC filters specifically, do you?

reviewed those minutes --

A Mm-hmm.

Q -- confirmed the accuracy of those minutes and what was discussed at the meeting that resulted in those minutes by your having your signature on it, right?

A Correct, yeah.

Q Mr. North also -- can I -- this is 16, right?

(Kandarpa Exhibit No. 16 was marked for identification.)

MR. LOPEZ: I don't have an extra copy of this because I didn't think this was going to come up, but you can -- you will see it on your screen.

BY MR. LOPEZ:

Q You have to look at it on -- at the screen for this one, Doctor.

A Okay.

Q See this Exhibit 16, do you see that this is an e-mail from you to John DeFord?

A Okay.

Q And I'll represent that the underlining and the highlighting were not on the original.

A Okay. I'm having a hard -- trouble reading it, but --

Q And that Mr. DeFord wrote -- writes back to you. Do you see where we are?

A Mm-hmm.

Q And do you see where it says on October -- on August 3, 2007, where you wrote: "I was also under the impression that I was under contract to BBA, but stand corrected per your note below. I am glad the findings will not be challenged. It might make it easier for me. I do not want any misunderstandings between BBA and/or Bard and/or me. Kris."

Do you see that?

A Yeah. Can I -- can I just look at it? I'm having -- I see that, but I'm having trouble --

Q Okay.

A Oh, yeah, I -- yeah. Okay. You want to finish and then I can look --

Q Yeah, then I'll let you --

A Okay, fine.

Q And then Mr. DeFord writes back to you: "This has unfortunately become a real mess.

Apparently, the Bard/BBA relationship is deteriorating on a host of studies (including EVEREST) where BBA has been contracted at Bard's CRO."

Did I read that correctly?

A Yes.

Q Were you able to see that?

A Yeah, I see that.

Q Okay. Now, I want to draw your attention to the bottom. I want to make sure you can read that. Can you see that clearly?

A Yeah, I see it. Okay. I'll have to read it again, but I see it.

Q Is there any way I can --

A I think it's just a reproduction -- it's okay. I'll look at it.

Q Well, I want to be able to -- the camera needs to see this clearly so the jury can read this too.

A Oh, I see.

MR. LOPEZ: Is there any way you can fix that? Because it's -- it's the focus.

BY MR. LOPEZ:

Q There we go. Is that better?

A Yeah, mm-hmm.
Q Okay. "It is my understanding" -- this is Mr. DeFord writing to you, correct?
A Mm-hmm.
Q And you know Mr. DeFord?
A Yes, I do.
Q Actually is it Dr. DeFord?
A He has a -- he's a Ph.D.
Q Ph.D.
"It is my understanding that you were contracted by Bard Peripheral Vascular (not BBA) as the Clinical Events Committee (CEC) for the study."
Do you say that?
A Yeah, I see that.
Q "I also understand that BBA has been handling all payments to you for your services as well as facilitating all interactions."
A Correct.
Q Do you see that?
A Yes.
Q Now, do you understand that Mr. DeFord or Dr. DeFord is a very high official at Bard?
A Yes.